Decision Memo for Ultrasound Diagnostic Procedures (CAG-00309R)

Decision Summary

CMS was asked to reconsider our current national coverage determination (NCD) on ultrasound diagnostic procedures. CMS has determined that there is sufficient evidence to conclude that esophageal Doppler monitoring of cardiac output for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization is reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act, and therefore, we are removing the past national non-coverage of cardiac output Doppler monitoring.

CMS will amend the NCD Ultrasound Diagnostic Procedures at section 220.5 of the NCD manual by adding "Monitoring of cardiac output (Esophageal Doppler) for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization" to Category I, and deleting "Monitoring of cardiac output (Doppler)" from Category II.

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Decision Memo

TO:	Administrative File: CAG #00309R Ultrasound Diagnostic Procedures
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SUBJECT: Final Coverage Decision Memorandum for Ultrasound Diagnostic Procedures

May 22, 2007

DATE:

I. Decision

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II. Background

Cardiac output (CO) refers to the volume of blood ejected from the heart over a period of time. It can be calculated by multiplying the stroke volume (SV, the amount of blood pumped by the left ventricle in one contraction) by the heart rate (HR, beats per minute), though other methods can be used to calculate CO (Fick technique, Indicator-dilution technique, Pulmonary artery catheterization with thermodilution).

For patients undergoing surgery or those in the intensive care units (ICUs), CO monitoring has been used to guide intravenous fluid replacement and pharmacologic therapy to maintain adequate organ perfusion. Alternatively, fluid management can be based solely on the clinical assessment of hemodynamic variables such as heart rate, systolic blood pressure, central venous pressure (CVP), and urine output, with no attempt to measure blood flow. However, in the majority of instances, critical care staff is often unable to correctly predict a patient's hemodynamic profile from the clinical examination alone (Connors, McCaffree, Gray 1983; Fein, Goldberg Walkenstein et al. 1984). Cardiac output estimation is essential in patients with evidence of inadequate tissue perfusion (O'Quin, Marini, 1983).

Measurement of blood flow allows calculation of cardiac output, which enables clinicians to more accurately administer fluids (colloid or crystalloid intravenous solutions) needed to achieve adequate tissue perfusion. If the cardiac output does not increase after such administration (a fluid challenge,) this may indicate that the upper limit of beneficial fluid administration has been achieved and that further fluid administration could lead to fluid overload manifest by venous congestion and possible post-operative pulmonary edema (RNAO, 2006). For patients who have cardiac decompensation, this can result in heart failure. It is also possible that marked hypovolemia (abnormally low levels of blood plasma) may lead to poor response to an initial fluid challenge. If this condition is not corrected, further hypotension can occur which may result in renal failure as well as other postoperative complications (Price, Sear, Venn, 2004; Shoemaker, Appel Kram et al 1992). A more detailed discussion of the complexities of fluid management is beyond the scope of this short summary.

Esophageal Doppler, a type of transesophageal echocardiogram monitoring device, is a minimally invasive alternative for measuring CO in ICU patients. It was first described in 1971 and has subsequently been refined by Singer as a means of continuously monitoring cardiac function in the ICU (Side, Gosling, 1971; Singer, Clarke, Bennett, 1989). When an ultrasound beam is directed at a column of flowing blood, the reflected sound waves shift in frequency. This phenomenon, commonly illustrated in science books with the example of the change in the sound of a train whistle as the train approaches and then travels away from the listener, is referred to as a Doppler shift.

The degree of this Doppler shift in clinical settings is proportional to the velocity of blood flow. Stroke volume can then be determined by multiplying the blood velocity during a systolic cycle by the ejection time (stroke distance) and by the cross-sectional area that the blood flows through. Doppler signals are obtained with an esophageal probe placed cephalad to the sternum and directed toward the ascending aorta. Esophageal Doppler monitoring has a number of advantages over the trancutaneous (through the skin) approach: the close proximity of the descending aorta to the esophagus provides an optimal window for obtaining Doppler signals; and once positioned the esophageal Doppler is stabilized by the esophagus, thus permitting continuous monitoring (Marik 1999).

A number of studies have documented that there is good correlation between the CO measured by esophageal Doppler and the Fick method, thermodilution technique, as well as other techniques for measuring CO (Huntsman, Stewart, Barnes et al 1983; Mark, Steinbrook, Gugino et al. 1986; Davis, Allen, Chant 1991; Cuschien Rivers, Caruso et al. 1998). Valtier and associates were able to demonstrate a 95% correlation between cardiac output measured via thermodilution and transesophageal Doppler technique (Valtier, Cholley, Belot et al. 1998).

In contrast to other techniques for measuring CO, the probe of the esophageal Doppler can be inserted within minutes and requires minimal technical skills, and is not associated with major complications. A number of studies have questioned the safety of pulmonary artery catheter (PAC), and have highlighted the time taken to insert this device (Connor, Speroff, Dawson, et al. 1996; Lefrant Muller Bruelle, et al. 2000). Esophageal Doppler provides information on cardiac preload, contractility, stroke volume and cardiac output. Potential limitations of esophageal Doppler include operator dependency, difficulties in probe placement, and the lack of central venous access.

III. History of Medicare Coverage

There has been one previous consideration of Ultrasound Diagnostic Procedures. The current NCD describes indications and limitations on coverage. Technologies are listed as either Category I (clinically effective, usually part of initial patient evaluation, may be an adjunct to radiologic and nuclear medicine diagnostic technique) or Category II (clinical reliability and efficacy not proven). Medicare coverage is only extended to the procedures listed in Category I. Techniques in Category II are considered experimental and are not covered. Monitoring of cardiac output (Doppler) is placed in Category II. Therefore, the use of esophageal Doppler monitoring to determine cardiac output and for hemodynamic management is not currently covered.

Current Request

Deltex Medical requests an expansion of coverage to include esophageal Doppler monitoring of cardiac output in those patient groups that have been studied; specifically, ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization. Deltex asserts in its request that the current NCD pre-dates the commercial availability of both the CardioQ and its predecessor devices (the EDM I and EDM II), much, if not all of the validation data, and all of the peer-reviewed, randomized controlled clinical trial data.

Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. § 1812 (Scope of Part A); § 1832 (Scope of Part B) § 1861(s) (Definition of Medical and Other Health Services). Esophageal Doppler for the purpose of monitoring cardiac output is considered to be within the following benefit categories: other diagnostic tests (§1861(s)(3)), inpatient hospital services (§1861 (b)), and physicians' services (§1861 (q)). This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

August 31, 2006	CMS accepts a formal request for reconsideration of Ultrasound Diagnostic Procedures for expanded coverage for monitoring cardiac output. A tracking sheet was posted on the web site and the initial 30 day public comment period commenced.
September 30, 2006	The initial 30 day public comment period ended. Four comments were received.
February 26, 2007	CMS posts the proposed decision memorandum and opens a 30 day public comment period. One comment was received.

V. FDA Status

Deltex Medical's CardioQ esophageal Doppler monitor was cleared for marketing in the United States by the FDA on August 6, 2003 via the 510(k) premarket notification process. The labeled indications for use of the device are as follows:

"The CardioQ cardiac output and fluid status monitoring system is designed to provide clinicians with real-time information about left-ventricular blood flow. The CardioQ is designed to operate in a clinical setting in which the patients are under general anesthesia or are sedated in the intensive care unit. The CardioQ offers the anesthetist and intensive care physician with beat-to-beat data on cardiovascular status and circulating blood volume, providing immediate feedback on the effect of any therapeutic intervention."

VI. General Methodological Principles

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A

In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

We are providing a summary of the evidence that we considered during our review.
A reasonable and necessary diagnostic test must provide information that is used by the treating physician to appropriately guide the management of the patient’s specific medical problem. A principal outcome of interest in assessing the utility of a diagnostic test for this purpose is its ability to improve health outcomes of persons who are tested.

B. Discussion of evidence reviewed

1. Question:

Is the evidence sufficient to conclude that hemodynamic monitoring with esophageal Doppler, when used by the treating physician to guide management of the patient's condition, improves health outcomes in Medicare beneficiaries who are ventilated in the ICU or who need intra-operative fluid optimization?

2. External technology assessments

CMS commissioned a technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ), which contracted the TA to ECRI. A final report of this TA was submitted to CMS on January 16, 2007.

In general, published studies examined the addition of esophageal Doppler monitoring to conventional techniques such as clinical assessment and CVP monitoring, rather than directly comparing one method to another. Analysis of the data revealed that clinically significant reductions in the rate of major complications and total complications occurred in surgical patients monitored with the addition of esophageal Doppler ultrasound-based cardiac output devices compared to conventional clinical assessment alone. Since no deaths occurred in either group, no conclusion could be reached concerning the relative mortality rates. The report concluded that the evidence was strong supporting the use of esophageal Doppler ultrasound-based cardiac monitoring during surgery to improve patients' outcomes.

Addressing another question (improved outcomes during hospitalization), the report found one study. The median quality of the study was high, while generalizability to the Medicare population was fair. The study sample size was small without a demonstrable large treatment effect on the outcomes of interest; no conclusions were reached addressing this question.

3. Internal technology assessments

CMS performed an extensive literature search utilizing PubMed for new randomized controlled trials (RCTs) and systematic ICU and operative patients. The literature search was limited to the English language and specific to the human population using search terms: Transesophageal echocardiogram, esophageal Doppler ultrasound, cardiac output monitoring, CardioQ, HemoSonic, TECO.

The current request for coverage of esophageal Doppler in the management of ICU and operative patients included eight documents which are listed below. Full citations are provided in the References section. A search in the Cochrane Library failed to reveal any systemic reviews evaluating the use of esophageal Doppler sound for the purpose of cardiac monitoring.

The literature is rich with controlled studies comparing the use of esophageal Doppler for cardiac monitoring with standard care for a number of medical conditions in the Medicare-aged population. This review will be restricted to controlled studies.

One of the early studies to evaluate the use of Doppler ultrasound for cardiac monitoring was performed by Mythen et al. (Mythen, Webb, 1995). In this study, 60 patients (American Society of Anesthesiologist [ASA]) grade III undergoing elective surgery for coronary artery bypass graft (CABG) or single heart valve replacement were randomized to either the control group (standard practice) or to the protocol group (standard practice plus 200 ml boluses of 6% hydroxyethyl starch solution to obtain maximum stroke volume estimated by esophageal Doppler system). Sample size was predetermined, and randomization was according to contents of a sealed envelope. Anesthetic technique (e.g., the use of standard volatile-based general anesthetics, lungs ventilated with 50% nitrous oxide), was consistent for each participant. Baseline demographic characteristics and duration of surgery was similar between groups. The results of the study revealed that the incidence of gut mucosal hypoperfusion was significantly reduced in the protocol group compared to the control group (7% vs. 56%, P< 0.01), as well as the number of complications developed (0 vs. 6 days, P=0.01), mean number of days spent in the hospital (6.4 vs. 10.1, P=0.011), and mean number of days spent in the ICU (1 vs. 1.7, P=0.023).

Sinclair and associates performed a prospective, randomized controlled trial on patients with femoral fractures, to assess whether intra-operative intravascular volume optimization improves outcomes and shortened hospital days (Sinclair, James, Singer, 1997). This study involved 40 patients greater than 55 years of age, with fractures of the femoral neck. After being screened using specific exclusion criteria, patients were individually randomized before induction of anesthesia by a sealed envelope technique to either protocol group (esophageal Doppler) or control group (conventional intraoperative fluid management). Sample size estimates (20 per group) were based on achieving an effect size of a 33% reduction in hospital stay for survivors in the group with optimized fluids during operation. Outcomes of interest included time declared medically fit for discharge, duration of hospital stay, mortality, as well as peri-operative hemodynamic changes. All patients received a standardized anesthetic, and oxygenation was maintained by intubation. All patients also received crystalloid, hydroxyethyl starch colloid, or blood to replace estimated fluid losses and maintain heart rate and blood pressure; protocol patients also received hydroxyethyl starch fluid challenges guided by Doppler measures of stroke volume and corrected flow time. Study of the hemodynamics parameters revealed that protocol patients received significantly more fluid per minute of operating time, had higher stroke volume, corrected flow time and cardiac output compared to the control group, though heart rates and blood pressure did not change between groups. Patients in the protocol group also had significantly shorter hospital stays (whether assessed by time spent in an acute hospital bed [10 vs. 18 days], number of days needed before deemed medically fit for discharge [10 vs. 15 days], and total hospital stay [12 vs. 20 days]). Mortality rates were similar between both groups. The authors attributed the better outcomes for the protocol patients due to prevention of peri-operative tissue oxygen debt as a result of esophageal Doppler monitoring.

Venn and associates also used a randomized controlled trial to investigate influence of the fluid challenge on duration of hospital stay and perioperative morbidity in patients with hip fractures (Venn, Steele, Richardson, et al. 2002). Ninety participants were randomized by the use of computer generated random numbers and an opaque sealed envelope into one of three groups: conventional operative fluid management (CON, n=29), and two groups receiving additional repeated colloid fluid challenges guided by central venous pressure (CVP, n=31) or esophageal Doppler ultrasonography (DOP, n=30). Inclusion/exclusion criteria were included in the study, and base-line characteristics were captured. Primary outcomes measures (time to medical fitness to discharge, hospital stay, postoperative mortality) and secondary outcomes (differences in intraoperative CVP measurements between CON and CVP, and severe hypotension between all three groups) were noted. Essential monitoring of the cardiovascular and respiratory system was commenced before induction and continued into the recovery period as per protocol. The results of the study revealed that greater fluid challenges occurred in the CVP group as well as the DOP group, compared to the CON group. As a result of this, both groups (CVP and DOP) had fewer episodes of intraoperative hypotension ($P<0.048$). Time to be deemed medically fit for discharge was also shorter in the DOP group (8 vs. 14 days) and the CVP group (10 vs. 14 days) compared to the conventional group. But the study failed to reveal any differences in acute orthopedic hospital stay days, total number of hospital days, or mortality between the 3 groups.

Using a nurse-delivered protocol, McKendry and associates performed a randomized controlled trial to compare the length of stay (LOS) in intensive care units (ICU) and hospital after cardiac surgery in patients receiving standard peri-operative care or optimization of circulatory status with the use of Doppler ultrasound in the first four hours postoperatively, as well as compare postoperative complications between the groups (McKendry, McGloin, Saberi, Caudwell, et al. 2004). Participants involved in the study were patients undergoing cardiopulmonary bypass surgery; 204 patients were assessed eligible. Of this number, 174 were either randomized to control group (conventional management) or allocated to optimization of circulatory status (protocol group). Conventional postoperative care did not involve monitoring cardiac output, but instead relied primarily on monitoring arterial and central venous pressure with markers of tissue perfusion such as urine output and arterial base deficit. Protocol group had esophageal Doppler monitoring followed by a treatment algorithm to increase stroke volume index to $\geq$35 ml/m^2 or greater using repeated colloid challenges. Sample size was based on a mean reduction of 3 days between both groups. An intent-to-treat analysis was performed. Randomization was performed by a priori computer generated sequence; 89 patients were assigned to the protocol group, while 85 patients were assigned to the control group (groups were matched for age, gender, weight, Parsonnet cardiac risk scores and surgery type). As stated in the protocol, if patients in either group were ready for extubation before four hours, a Doppler reading was made before removal of the endotracheal tube. The results of the study revealed that, although stroke volume, cardiac index and use of colloid were well matched at baseline, they were significantly greater in the protocol group at four hours; use of inotropes were similar between both groups. Also in the protocol group, the mean number of days in the ICU was reduced from 3.2 to 2.5 (a 23% reduction though not statistically significant), the mean duration of hospital stay in this group was reduced from 13.9 days to 11.4 days (18% reduction), and a reduction in median duration of stay from 9 to seven days. Protocol participants also showed a trend toward fewer major postoperative complications compared to the control group (e.g., atrial fibrillation, chest infections, acute renal failure, etc.).

Wakeling and associates assessed whether or not using intra-operative esophageal Doppler guided fluid management to minimize hypovolemia would result in reduced hospital and the time before return of gut function after colorectal surgery (Wakeling, McFall, Jenkins, Woods, et al. 2005). This single center, blinded prospective controlled study consisted of 128 consecutive patients who were randomized to either conventional management (routine cardiovascular monitoring and CVP monitoring), or esophageal Doppler guided monitoring of additional colloid administration, using sequentially numbered sealed envelopes technique. Outcomes of the study included duration of postoperative hospital stay, as well as time taken until patient was able to tolerate a full diet. Inclusion/exclusion criteria as well as base-line demographics were noted. Sample size was based on predetermined effects size for both outcomes. Patients were intubated and ventilated to normocapnia throughout the operation; standard monitoring included ECG, pulse oximetry, capnography, and non-invasive arterial pressure. The results of the study revealed that the median postoperative hospital stay for esophageal Doppler group was 10 days, compared to 11 days for the conventionally managed group ($P< 0.05$, a 13% reduction), and the median time to tolerate full diet was 6 days for the Doppler group while 7 days for the control group ($P<0.01$). Patients in the Doppler guided group were given a significantly greater volume of intravenous colloid than controls, and the Doppler group achieved higher cardiac outputs and stroke volume at the end of the operation than did the control group. Nine of the patients in the Doppler group experienced gastrointestinal morbidity (e.g., infections, renal, etc) compared to 29 in the control group.

Noblett and associates evaluated the use of Doppler monitoring in patients undergoing colorectal resection (Noblett, Snowden, Shenton, Horgan, 2006). In this double-blinded study, patients were randomized to either the control group (n= 52), which consisted of standard treatment-peri-operative fluid at the discretion of the anesthesiologist, or randomized to the protocol group (n=51) in which additional colloid boluses were based on Doppler assessment. Primary outcomes measures (length of post-operative hospital stay) as well as secondary outcomes measures (e.g., morbidity, return of gastro-intestinal function as well as cytokine markers of systemic inflammatory response) were monitored. All anesthetic interventions were at the discretion of the consultant anesthetist responsible for perioperative management of the patient. Routine perioperative monitoring included ECG, pulse oximetry, end-tidal carbon dioxide monitoring, and non-invasive or invasive blood pressure monitoring. There were no differences found in patient demographics, risk indices, or duration and type of procedure (rectal resection vs. laparoscopic resection) between both groups. Analysis of the results revealed that patients in the protocol group had significantly reduced time to fitness for discharge (median 6 vs. 9 days, P=0.003), and actual discharge (7 vs. 9, P=0.005) days. Though there was no difference in lower gastrointestinal function assessed by return of bowel activity, the study did reveal that the protocol group was able to tolerate diet significantly earlier than the control group (P=0.029), and cytokine markers of inflammation (IL-6 concentration) were significantly different between protocol and control group (P=0.034). Intermediate or major complications were less frequent in the Doppler-guided group (1 vs. 8, P=0.043), including unplanned admission to the critical care unit (0 vs.6, P=0.012).

Conway and associates evaluated the use of Doppler monitoring in patients undergoing major bowel surgery (Conway, Mayall, Abdul-Latif, et al. 2002). Authors of this study wanted to determine the impact of Doppler-guided fluid optimization on hemodynamic parameters, peri-operative morbidity, as well as length of hospital stays. In this study, 57 patients were randomized to either a control group which used standard care protocol (n= 28; intra-operative fluid at the discretion of a non-investigating anesthesiologist), or randomized to the protocol group (n= 29; standard care along with fluid challenges guided by esophageal Doppler monitoring). The study revealed that, although the protocol group did receive more intra-operative colloid (mean 28 vs. 19.4, P=0.002), had higher cardiac output than the control group (6.1 vs. 5.0, P <0.05), and less morbidity (5 control participants required post-operative critical care admission vs. none in the protocol group, P= 0.02), there were no significant differences in hospital length of stay. The author attributes this lack due to underpowering.

Using a prospective randomized design, Gan and associates also studied patients undergoing major surgery to assess the effect of goal-directed intra-operative fluid administration on length of post-operative hospital stay (Gan, Soppitt, Maroof, et al. 2002). This involved 100 patients with ASA physical status I, II, and III who were undergoing major elective surgery, urologic, or gynecologic surgery with an anticipated blood loss of greater than 500 ml. Following induction of anesthesia, patients were randomized to either protocol group (boluses of fluid were guided by an algorithm depending on the Doppler estimations of stroke volume and corrected flow time) or control group (anesthesia care provider was not given results of Doppler reading, but instead relied on monitoring change in heart rate, systolic blood pressure, central venous pressure, and urine output) using a random number generator in sealed envelopes. Both groups were well matched with regards to demographics, ASA status, duration of anesthesia and other factors. The results of the study revealed that the protocol group had a significantly higher stroke volume and cardiac output compared to the control group, and a shorter hospital stay (5 +/- 3 vs. 7 +/- 3 days [mean +/- SD], 6 vs. 7 days [median] respectively (P=0.03). Fewer protocol patients experienced severe post-operative nausea and vomiting (P=0.01), and were able to tolerate an oral solid regimen earlier than the control group.

Chytra and associates also compared the two forms of management in multiple-trauma patients (Chytra, Pradl, Bosman, Pelnar, et al. 2007). In this single-center randomized trial, the study's objective was to examine the effect of esophageal Doppler-guided fluid management during the first 12 hours after ICU admission on blood lactate levels, organ dysfunction development, infectious complications, and length of ICU and hospital stays in comparison with standard hemodynamic management (control group). A sample size of 75 patients in each group was predetermined based on an effect size of 0.6 mmol/l per 24 hours. An intent-to-treat analysis was performed. The groups were well matched for age, gender, SOFA score at the time of ICU admission, APACHE II as well as ISS scores, and type of injuries. The study revealed that after the 12-hour study period, blood lactate levels in the Doppler group of patients was statistically lower (2.92 mmol/l versus 3.22 mmol/l, p=0.003) compared to patients that received conventional management. Also the rate of administration of norepinephrine was lower in the Doppler group compared to conventional treatment group (RR =0.56, p=0.018). The difference in lactate levels between the Doppler and control group change very little after 24 hours of ICU stay. Though no differences in SOFA levels were noted during admission, and no organ dysfunction was noted between the two groups, fewer infectious complications were noted in the Doppler group compared to the control (RR=0.5491, p=0.032). There was a noted reduction in median duration of hospital stay (14 days versus 17.5 days, p=0.045), as well as reduction in ICU days (7 versus 8.5, p=0.031). Limitations of the study included a relatively small size cohort, non-blinding, study conducted at only one center, and younger age population (average age in experimental group was 33, the average age in control group was 40) making it difficult to generalize to the Medicare population.

4. MedCAC

A Medicare Evidence Development and Coverage Advisory Committee (MedCAC) meeting was not convened on this issue.

5. Evidence-based guidelines

No evidence-based guidelines are available for the use of esophageal Doppler ultrasound for the purpose of monitoring cardiac output.

6. Professional Society Position Statements

We have not found nor received professional society position statements on this topic.

7. Expert Opinion

We have not received any expert opinions on the use of esophageal Doppler ultrasound for the purpose of monitoring cardiac output.

8. Public Comments

Initial Comment Period: August 31, 2006 – September 30, 2006

CMS received a total of four comments during the first public comment period. All of the comments were from physicians. All of the comments supported coverage of esophageal Doppler monitoring for cardiac output and were based on commenters professional experience with the use of esophageal Doppler monitoring in managing patients in the intraoperative and ICU settings.

Public comments received as of September 30, 2006, are summarized below:

Two physicians indicated that since the introduction of esophageal Doppler monitoring in their facilities, they have seen a decrease in the use of pulmonary artery catheters as well as central venous catheters. They indicated that the esophageal Doppler monitor is more efficient and safer to use than the pulmonary artery catheter. In their experience, they reported no complications of use with esophageal Doppler monitoring.

One commenter reported that the data are somewhat different, but with experience and knowledge, the esophageal Doppler monitor is an excellent guide for patient management. Similarly, another commenter indicated that he found the esophageal Doppler monitor to be invaluable because it provides real time, rapidly obtained, accurate and reliable information.

One commenter indicated that he has been able to optimize patients for some surgeries to the point that ICU care is no longer the routine but the exception.

Second Comment Period: February 26, 2007 – March 28, 2007

CMS received four comments during the initial public comment period, which were discussed in our proposed decision memorandum.

CMS received one comment during the 30-day public comment period following publication of the proposed decision memorandum. This comment was from the requestor and provided one additional reference for review.

Response: CMS has reviewed the additional article and has included a discussion in the analysis section of this decision memorandum. This article reports the results of a clinical trial of esophageal Doppler in trauma patients.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” §1862(a) (1) (A). This section presents the agency’s evaluation of the evidence considered and conclusions reached for the assessment question:

Question

Is the evidence sufficient to conclude that hemodynamic monitoring with esophageal Doppler, when used by the treating physician to guide management of the patient's condition, improves health outcomes in Medicare beneficiaries who are ventilated in the ICU or who need intra-operative fluid optimization?

As a diagnostic test, hemodynamic monitoring with esophageal Doppler affects health outcomes through changes in disease management brought about by physician actions taken in response to test results. Such actions may include decisions to treat or withhold treatment, to choose one treatment modality over another, or to choose a different dose or duration of the same treatment. 42 CFR 410.32(a) states in part, "…diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."

Our analysis focused on studies that used a randomized clinical trial design because this type of research design provides the strongest evidence of causal linkages (see Appendix A). Because there is a sufficient number of randomized clinical trials available upon which to base this coverage determination, we did not review studies that have weaker methodologic designs. Thus, we have minimized the potential impact of confounding that could occur between variables studied, as well as other threats to internal validity (e.g., selection bias, reliability of measures and procedures, etc.). In each study, consistent definitions of terms, measurement procedures, as well as diagnostic criteria were all clearly stated and appropriate. All study protocols included a treatment algorithm establishing a standard treatment in response to specific hemodynamic findings, which directed physician fluid management for all patients with an esophageal Doppler. We have determined that this use is consistent with the requirements in 42 CFR 410.32 cited above.

All studies used randomization, and more specifically most describe the randomization process. Most of the studies had adequate sample sizes and described the details in determining that sample size. Inclusion as well as exclusion criteria were stated in each study. Only one study had a patient population which was not generalizable to the Medicare population (Gan, Soppitt, Maroof, El-Moalem, Robertson, Moretti, Dwane, Glass, 2002). All of the studies had baseline population characteristics which were similar, and all used standardized instruments to measure outcomes. Intent-to treat analysis was also followed in each study, and appropriate statistical analysis was performed. All of the studies demonstrated that, compared to patients receiving standard therapy, patients who were managed with esophageal Doppler had adequate CO (as opposed to evidence of hypovolemia), shorter hospital length of stays (the only exception to the latter was the Connor study), and generally, decreased complications.

As noted earlier in this NCD, CMS commissioned AHRQ to perform a technology assessment on this topic. That analysis revealed that patients had improved outcomes during surgery and hospitalization when therapeutic management was based on esophageal Doppler ultrasound-based cardiac monitoring in addition to conventional clinical assessment. Though the criteria used in the assessment by AHRQ were more specific (i.e. improved outcomes during surgery and hospitalization), our findings are essentially consistent. Although evidence varied in each of the particular techniques studied, esophageal Doppler used in conjunction with existing techniques generally was found to have favorable patient outcomes and decreased hospital length of stays in comparison to conventional methodologies alone. Our assessment did not confine itself to the improved outcomes during surgery or hospitalization, but instead asked the general question if there was sufficient evidence that demonstrated whether or not hemodynamic monitoring using esophageal Doppler resulted in improved health outcomes for Medicare beneficiaries, compared to conventional management.

There were a number of different types of major surgeries performed for different conditions employed in these studies (e.g., femoral fractures, hip fractures, CABG, heart valve replacement, bowel surgery, and GYN surgery), and both university teaching hospitals, as well as general hospitals, were the sites for these studies. Most patients were artificially ventilated perioperatively. We conclude that the benefit attributed to the use of esophageal Doppler monitoring is generalizable to beneficiaries undergoing major surgery and beneficiaries ventilated in the ICU setting, in both community hospitals and major university centers. In summary, we believe that the published literature demonstrates sufficient evidence that hemodynamic monitoring with esophageal Doppler does result in improved health outcomes for Medicare beneficiaries.

IX. Conclusion

CMS was asked to reconsider our current national coverage determination (NCD) on ultrasound diagnostic procedures. CMS has determined that there is sufficient evidence to conclude that esophageal Doppler monitoring of cardiac output for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization is reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act and therefore, we are removing the past non-coverage of cardiac output Doppler monitoring.

CMS will amend the NCD Ultrasound Diagnostic Procedures at section 220.5 of the NCD manual by adding "Monitoring of cardiac output (Esophageal Doppler) for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization" to Category I, and deleting "Monitoring of cardiac output (Doppler)" from Category II.

Appendices [PDF, 76KB]

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